UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and ANTHONY CUTONE, Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	CIVIL ACTION No. 04-CV-12725 (MBB)

JOINT MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT FOR PURPOSES OF SETTLEMENT

Plaintiffs Kimberly and Anthony Cutone ("plaintiffs") and Defendant Eli Lilly and Company ("Lilly"), by and through counsel, hereby move for leave to file a Second Amended Complaint adding the claims of plaintiffs' minor child, Adriana Bella Cutone, for the purposes of settlement. As grounds for their joint motion, the parties state:

1. This case concerns a pharmaceutical/products liability claim alleging Plaintiff Kimberly Cutone was injured as a result of *in utero* exposure to Diethylstilbestrol ("DES"). Mrs. Cutone allegedly suffered uterine and cervical malformations, as a result of her exposure, causing her to suffer miscarriages and infertility.

2. On November 9, 2004, subsequent to the filing of plaintiffs' original Complaint, Mrs. Cutone gave birth to Adriana at 31-weeks gestation. Plaintiffs believe that Adriana's premature birth was caused by Mrs. Cutone's exposure to DES; Lilly contests plaintiffs' belief. Plaintiffs are concerned that Adriana may be exhibiting developmental delays as a result of her prematurity.

3. On November 29, 2005, the Court granted plaintiff's consent motion to amend their Complaint adding Adriana's claims. *See* Docket No. 57; Nov. 29, 2005 Electronic Order Granting Motion for Leave. Plaintiffs subsequently decided not to pursue Adriana's claims in the context of this lawsuit. A Stipulation of Dismissal Without Prejudice as to Adriana's claims was docketed on February 7, 2006. Docket No. 65.

4. The parties mediated this case on March 20, 2007. Lilly's offer of settlement was contingent upon obtaining a general release with respect to Adriana's claims. Plaintiffs agreed that Adriana's claims could be added to this action for the purposes of settlement.

WHEREFORE, the parties respectfully request that their Joint Motion for Leave to File a Second Amended Complaint for Purposes of Settlement be GRANTED.

Respectfully submitted,

KIMBERLY CUTONE and ANTHONY CUTONE, her husband,

By Their Attorneys,

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ELI LILLY AND COMPANY,

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Dated: April 2, 2007

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FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and ANTHONY CUTONE, Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	CIVIL ACTION No. 04-CV-12725 (MBB)

SECOND AMENDED COMPLAINT
(DES Litigation - Products Liability, Punitive Damages)

1. Jurisdiction is founded upon 28 U.S.C. §1332.

2. Plaintiffs are citizens and residents of the United State of Massachusetts. Defendant. Eli Lilly and Company is a citizen of the United States and has their principal place of business in the State of Indiana. The amount in controversy exceeds $75.000.00, exclusive of interest and costs.

3. Plaintiff Kimberly C. Cutone brings this suit individually and as the mother, guardian and next friend of Plaintiff Adrianna Bella Cutone, a minor. Plaintiff Anthony Cutone suit sounds in loss of consortium.

4. Defendant Eli Lilly and Company is the manufacturer of Diethylstilbestrol ("DES"). *who* sold and promoted the drug to Virginia Camporesi, the mother *of* the Plaintiff Kimberly C. Cutone, in 1969 and 1970 in Massachusetts.

COUNT I
(Negligence - Kimberly C. Cutone et al. v. Eli Lilly and Company)

5. During her pregnancy with Plaintiff Kimberly C. Cutone in 1969-1970, the mother of the Plaintiff Kimberly C. Cutone, purchased and ingested DES in the state of Massachusetts exposing her daughter to same during her formation. Said drug was prescribed by her treating obstetrician during the pregnancy. The drug was sold by Defendant Eli Lilly and Company.

6. As a result of Plaintiff Kimberly C. Cutone 's embryonic exposure to DES. she suffered injuries, including. but not limited to, uterine and cervical malformations. resulting in the inability to carry a pregnancy to term, infertility, miscarriages, the premature birth of minor Plaintiff Adrianna Bella Cutone, medical expenses for care and treatment, physical and mental pain, and the inability to have the family she desired.

7. Said injuries were the result of the negligence of Defendant Eli Lilly and Company, including, but not limited to, failure to test, failure to warn, over-promotion of DES, and failure to report adverse studies regarding the safety and efficacy of DES.

COUNT II
(Strict Liability - Kimberly C. Cutone v. Eli Lilly and Company)

8. All of the allegations contained in paragraphs 1 though 7 are hereby realleged.

9. DES is, and at all times relevant to this action was, an unreasonably dangerous and defective drug when used by pregnant women for its advertised and intended purpose as a preventative of miscarriage.

10. Defendant Eli Lilly and Company knew. or should have known. that pregnant women and their attending physicians could not realize and could not detect the dangerous and

harmful nature of DES. Clear warnings as to the doubtful efficacy of DES and dangers to unborn children should have been disseminated to overcome Defendant's extensive advertising campaigns proclaiming the safety and efficacy of DES.

11. As a result of Defendant Eli Lilly and Company's marketing and promotion of said defective and unreasonably dangerous drug. Plaintiff Kimberly C. Cutone was unreasonably exposed to DES as an unborn child and has suffered injury. loss, and damages as aforesaid.

12. By reason of having marketed and promoted DES in its defective and unreasonably dangerous condition, Defendant Eli Lilly and Company is strictly liable to Plaintiff Kimberly C. Cutone for her DES-related injuries. losses. and damages.

COUNT III
(Breach of Warranty - Kimberly C. Cutone v. Eli Lilly and Company)

13. All of the allegations contained in paragraphs 1 through 12 are hereby realleged.

14. At all times relevant to this action, Defendant Eli Lilly and Company marketed and promoted DES accompanied by implied and express warranties and representations to physicians and their patients that the drug was efficacious as a miscarriage preventative, and was safe for pregnant women and their unborn children if used as directed for such purposes.

15. Defendant Eli Lilly and Company knew, or should have known, that pregnant women. including the mother of Plaintiff Kimberly C. Cutone and her attending physicians. were relying on Defendant's skills and judgments, and the implied and express warranties and representations.

16. At all. times relevant to this action, these implied and express warranties and representatives were false, misleading. and unfounded. In fact. DES was a misbranded drug in violation of federal law, and was neither safe nor efficacious as a miscarriage preventative.

17. As a direct result of the breach of warranties by the Defendant Eli Lilly and Company, Plaintiff Kimberly C. Cutone has been injured as aforesaid.

COUNT IV
(Misrepresentation - Kimberly C. Cutone v. Eli Lilly and Company)

18. All of the allegations contained in paragraphs 1 through 17 are hereby realleged.

19. Defendant Eli Lilly and Company represented to pregnant women, including the mother of Plaintiff and her attending physicians, in promotion campaigns. advertisements. labeling. and literature that DES was safe, effective. and adequately tested, which representations were made and publicized with the purpose and intent of having physicians and their patients rely on them.

20. The mother of the Plaintiff Kimberly C. Cutone and her attending physicians, did in fact, rely on Defendant Eli Lilly and Company's representations in its advice about purchase, use, and consumption of DES.

21. At all, times relevant to this action, these representations were known to Defendant Eli Lilly and Company to be false or they were made by Defendant in conscious, reckless and/or unreasonable disregard of facts available to Defendant, indicating a lack of efficacy and a danger to pregnant women and their unborn children.

22. As a direct result of said false representations by Defendant Eli Lilly and Company, Plaintiff Kimberly C. Cutone was injured as aforesaid.

COUNT V
(Negligence - Adrianna Bella Cutone, a Minor v. Eli Lilly and Company)

23. Plaintiff Kimberly C. Cutone brings this suit as mother, guardian and next friend of Adrianna Bella Cutone. a minor, who was injured as a result of her premature birth, as a result of his mother's. Plaintiff Kimberly C. Cutone's, exposure to DES in utero.

24. The drug DES is a transplacental teratogen capable of crossing the placenta and entering the blood stream of the developing fetus. The reproductive tract of the developing female is sensitive to the estrogenic stimulation of DES (a synthetic estrogen promoted, manufactured, sold and distributed by Defendants). In 1969-1970, Virginia Camporesi, the minor Plaintiffs grandmother. ingested DES, which caused her daughter's developing reproductive tract to become deformed, marred and stunted. This defect is such that the organs (uterus and cervix) are not capable of holding back. restraining or delaying pregnancy. The infant. Adrianna Bella Cutone, was born 9-10 weeks early, at 30/31 weeks gestation, because of her mother's DES-injured birth uterus / cervix, which she shared for the 30/31 weeks of her gestation. As a result, Adrianna Bella Cutone was born prior to full maturity of her lungs, brain and body, resulting in permanent and severe injuries, including. but not limited to developmental delays. neurological disorders and deficits, all of which have caused and continue to cause pain and suffering, medical and surgical expenses, loss of future earnings, therapeutic expenses and loss of enjoyment of life.

25. Said injuries were the result of the negligence of Defendant Eli Lilly and Company, including, but not limited to, failure to test, failure to warn, over-promotion of DES, and failure to report adverse studies regarding the safety and efficacy of DES.

COUNT VI
(Strict Liability - Adrianna Bella Cutone, a Minor v. Eli Lilly and Company)

26. All of the above allegations are realleged and incorporated herein by reference.

27. Prior to 1969-1970, the date the Plaintiff's birth uterus / cervix was injured, numerous reports were received in the medical and scientific literature to the effect that:

a. DES, as well as many other chemicals, could cross the placenta;

b. DES and other drugs and chemicals that crossed the placenta could effect and injure the developing fetus;

c. DES was a "target" drug, i.e., it targeted or effected primarily the estrogen receptor organs of the female reproductive tract, whether the primary or secondary exposed person;

d. DES had a potent cellular effect on female reproductive organs;

e. DES was not efficacious and of no value in the prevention of miscarriages for which it was promoted by Defendant:\

f. DES was a teratogen to the reproductive tract of fetal animals such as mice, rats and mink when ingested by their mothers during pregnancy;

g. Raised questions about the toxicity of DES to the developing fetal female reproductive organs.

28. Based on the above reports, it was foreseeable, expected and knowable by Defendant Eli Lilly and Company that DES would expose the daughters of the pregnant women who were ingesting the drug to stunt and deform their cervix and uteri and that it was foreseeable, knowable and expected in 1969-1970 that DES given to pregnant women could and would stunt and deform their grandchildren's birth uterus, causing prematurely with resulting injury of the grandchildren.

29. DES is, and at all times relevant to this action was, an unreasonably dangerous and defective drug when used by pregnant women for its advertised and intended purpose as a preventative of miscarriage.

30. Defendant Eli Lilly and Company knew, or should have known. that pregnant women and their attending physicians could not realize and could not detect the dangerous and harmful nature of DES. Clear warnings as to the doubtful efficacy of DES and dangers to unborn children should have been disseminated to overcome Defendant's excessive advertising campaigns proclaiming the safety and efficacy of DES.

31. As a result of Defendant Eli Lilly and Company's marketing and promotion of said defective and unreasonably dangerous drug, Plaintiffs mother, Kimberly C. Cutone, was unreasonably exposed to DES as an unborn child and the minor Plaintiff has suffered injury. loss and damages as aforesaid.

32. Due to having marketed and promoted DES in its defective and unreasonably dangerous condition, Defendant Eli Lilly and Company is strictly liable to the minor Plaintiff for his DES-caused injuries, losses and damages.

COUNT VII
(Breach of Warranty - Adrianna Bella Cutone, v. Eli Lilly and Company, et al)

33. All of the above allegations are realleged and incorporated herein by reference.

34. At all times relevant to this action, Defendant Eli Lilly and Company marketed and promoted DES accompanied by implied and express warranties and representations to physicians and their patients that the drug was efficacious as a miscarriage preventative, and was safe for pregnant women and their unborn children if used as directed for such purposes.

35. Defendant Eli Lilly and Company knew. or should have known that pregnant women, including the grandmother of Plaintiff and her attending physicians, were relying on Defendant's skill and judgment, and the implied and express warranties and representations.

36. At all. times relevant to this action, these implied and express warranties and representatives were false. misleading, and unfounded. In fact, DES was a misbranded drug in violation of federal law, and was neither safe nor efficacious as a miscarriage preventative.

37. As a direct result of the breach of warranties by the Defendant Eli Lilly and Company. minor Plaintiff has been injured as aforesaid.

COUNT VIII
(Misrepresentation - Adrianna Bella Cutone v. Eli Lilly and Company)

38. All the above allegations are realleged and incorporated herein by reference.

39. Defendant Eli Lilly and Company represented to pregnant women, including the grandmother of Plaintiff and her attending physicians, in promotion campaigns, advertisements, labeling, and literature that DES was safe, effective, and adequately tested, which representations were made and publicized with the purpose and intent of having physicians and their patients rely on them.

40. The grandmother of the plaintiff and her attending physicians, did in fact. rely on Defendant's representations in its advise about purchase. use, and consumption of DES.

41. At all. times relevant to this action, these representations were known to Defendant to he false or they were made by Defendant Eli Lilly and Company in conscious. reckless and/or unreasonable disregard of facts available to Defendant, indicating a lack of efficacy and a danger to pregnant women and their unborn children.

42. As a direct result of said false representations by Defendant Eli Lilly and Company. minor Plaintiff was injured as aforesaid.

COUNT IX
(Punitive Damages)

43. The acts of the Defendant Eli Lilly and Company were gross, wanton and intentional in that Defendant, at the time of Plaintiffs exposure, had actual and constructive notice that DES crossed the placental barrier and adversely affected and stunted the morphology and embryologic development of the exposed female fetus. Additionally, the Defendant Eli Lilly and Company knew or should have known that DES was ineffective. of no use and provided no benefit to the pregnant mother. Nonetheless, the Defendant knowingly and intentionally promoted DES for use in pregnancy as safe and effective to prevent the threat of miscarriage disregarding the published literature that warned of the risks and criticized its efficacy. The Defendant Eli Lilly and Company intentionally, maliciously and wantonly promoted DES for use in maintaining pregnancy as the most "effective" therapy to prevent miscarriage and even recommended its use prophylactively even where no symptoms or signs of a threatened miscarriage appeared. Additionally. the Defendant fraudulently deceived the Food and Drug Administration and the obstetrical profession and Plaintiffs by knowingly and intentionally withholding adverse literature and studies and submitting only favorable reports. which it knew originated in erroneous studies with incompetent investigators using poorly designed test methods.

COUNT IX
(Loss of Consortium - Anthony Cutone v. Eli Lilly and Company, et. al.)

44. All the above allegations are realleged and incorporated herein by reference.

45. Plaintiff. Anthony Cutone is the husband of Kimberly C. Cutone. As a result of the negligence, strict liability. breach of warranty, and misrepresentation of Defendant Eli Lilly

and Company as aforesaid. Plaintiff Anthony Cutone has been deprived of the love, services and affection of his wife, Kimberly C. Cutone.

WHEREFORE, Plaintiff Kimberly C. Cutone, individually, demands judgment against Defendant in the sum of $1 Million ($1,000,000.00) in compensatory damages and $1 Million ($1.000.000.00) in punitive damages. plus costs.

WHEREFORE, Plaintiff Kimberly C. Cutone. as Mother, Guardian and Next Friend of Adrianna Bella Cutone, a minor. demands judgment against Defendant for $10 Million ($10,000.000.00) in compensatory and punitive damages, plus costs.

WHEREFORE, Plaintiff Anthony Cutone, individually, demands judgment against Defendant in the sum of $500 thousand ($500,000.00) in compensatory damages. and $500 thousand ($500.000.00) in punitive damages, jointly and severally, plus costs.

DEMAND FOR JURY TRIAL

Plaintiff hereby demand a trial by jury as to all issues of material facts.

Respectfully submitted,

/s/ Erica Tennyson (by permission)
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Dated: April 2, 2007

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[PROPOSED] ORDER

Upon consideration of the parties' Joint Motion for Leave to File a Second Amended Complaint for Purposes of Settlement, and for good cause shown, it is by this Court this _____ day of _____ 2007, hereby

ORDERED, that the parties' Joint Motion for Leave to File a Second Amended Complaint for Purposes of Settlement be and the same hereby is, GRANTED.

_____
Hon. Marianne B. Bowler
U.S. Magistrate Judge